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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,423

01/30/2006

Arunendra Nath Lahiri Majumder

4544-051674

1726

28289 7590 02/25/2008

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

02/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,423	<b>Applicant(s)</b> MAJUMDER ET AL.	
	<b>Examiner</b> MALGORZATA A. WALICKA	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

The application was filed June 10, 2005 as a 371 of the international application PCT/IN2003/0065 filed March 21, 2003 having a valid priority to the Indian application 1250/Del//02 filed December 2002. Claims 1-6 are pending and under examination.

### **Detailed Action**

#### **Priority**

This application claims the benefit of the Indian application 1250/Del//02 filed December 2002. Priority of the instant claims to the Indian application has not been granted, because the amino acid sequence of SEQ ID NO: 3 of the instant 371 application that is the claimed salt-tolerant L-myo-inositol 1-phosphate synthase of wild rice is different than that of the Indian application. It differs in four position from the sequence disclosed in the Indian application 1250/Del//02 that is presented in extenso in claim 1. The sequence recited in claim 1 differs from the sequence listed as SEQ ID NO: 3 in the paper and computer form filed with the instant application as follows: W42Y, W69Y, T345M, and P376L. However, the nucleotide sequence of SEQ ID NO: 1, differs only in one position, A35G.

#### **Objections**

##### Claims

In claim 1, please correct typographical and spelling errors in lines 2 and 3.

In claim 2, please delete “of “ after “comprises” in the second line.

In claim 2, line 1, delete ‘coding’.

In claim 5, please place the coma properly in line 1; delete the word “the” before “said” in line 1, and correct typographical errors in line 2.

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In claim 6 please write “urea” with a smaller case ‘u’ and correct typographical errors in lines 2 and 3.

Claims 1-6, at different places recite ‘nucleotide sequences’ in the plural, while there is only one nucleotide sequence. Correction is required.

### Specification

The specification is replete with spelling and typographical errors, e.g., page 2 in (i): “( PINO1)”; page 3, line 3: “8M Urea,0.5 M NaCl, 20mM Tris-HCl ,pH 7.5,10”.

The disclosure is objected to for using the term “gene” to mean cDNA.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

### **Sequence rules**

Claims 1-6 refer to DNA and amino acid sequence presented in claim 1. The specification also present DNA and amino acid sequences without referring to their sequence identification number. The sequence rule 37 CFR § 1,821 paragraph (d) reads: “where the description or claims of a patent application discuss a sequence listing that is set forth in the “Sequence Listing” with paragraph (c) of this section, reference must be made to the sequence by the use of the assigned identifier (written as SEQ ID NO: 1 for DNA and SEQ ID NO: 3 for the protein) in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Therefore, as per rule cited above,

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claims 1-6 should be amended to recite their sequence identification numbers or additionally add to their sequence identification numbers in parenthesis.

## Rejections

35 USC 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is confusing because a nucleotide sequence cannot comprise “two additional amino acids”. A DNA sequence is built of nucleotides and not of amino acids. It seems that Applicants’ intention was to emphasize that the protein encoded by DNA of claim 1, i.e., DNA of SEQ ID NO: 1, is two amino acid longer than that originated from rice. Rewording the entire claim is suggested to clarify what is being claimed.

Claim 3 and dependent claims are rejected under this paragraph. Claim 3 is not directed to a process of obtaining a salt-tolerant L-myo-inositol 1-phosphate synthase **gene**, but to a process of obtaining **cDNA** encoding said synthase. **Applicants have**

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**not isolated a genomic sequence** of the plant L-myo-inositol 1-phosphate synthase that is why the claims are confusing.

Claims 3-6 are confusing, because all of them are directed to the process of claim 3, however, claim 4 depends upon claim 3 and includes an expression vector comprising cDNA encoding L-myo-inositol 1-phosphate synthase, claim 5 to E. coli cell transformed with said vector for expression of PINO1, and claim 6 to the PINO1 expressed in the E.coli transformed with PINO1 cDNA. Claims 4-6 are included in the rejection for not correcting the defect present in the base claim 3.

35 USC 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6 are rejected for lacking a proper written description of structure of the claimed products, i.e, cDNA identified in the sequence listing as SEQ ID NO: 1 and protein of SEQ ID NO: 3. SEQ ID NO: 3 of the instant 371 application that identifies the claimed salt-tolerant L-myo-inositol 1-phosphate synthase of wild rice is different than that presented in claim 1 in four positions: W42Y, W69Y, T345M, and P376L, wherein the amino acid preceding the number is that presented in claim 1. However, the nucleotide sequence of SEQ ID NO: 1, differs only in one position, A35G. As such, the claimed products are not sufficiently described so that a skilled artisan was convinced that applicants were in possession of the claimed invention at the time of filing.

Furthermore, claims 3-6 are rejected as directed to the process of obtaining a salt-tolerant L-myo-inositol 1-phosphate synthase **gene** of *Porteresia coarctata*. **Applicants have not isolated a genomic sequence** of the plant L-myo-inositol 1-phosphate synthase. No sequence structure of the gene or cDNA is evident or described. The genomic sequence including regulatory sequence and all exons and introns is no disclosed by the specification. Applicants teach only cDNA encoding the enzyme. *Porteresia coarctata* is a plant, i.e., an eukaryotic organism, therefore, its cDNA is not equivalent to its gene as is the case in prokaryotic organisms.

### **35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement

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thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-6 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claim 1 to recite wording such as "An isolated salt tolerant ....".

## **Conclusion**

No claim is in condition for allowance, nevertheless the invention is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached on (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for



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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.  
Art Unit 1652  
Patent Examiner

/Tekchand Saidha/  
Primary Examiner, Art Unit 1652

## **2. Examiner's amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

- (a) Please cancel claim 32.
- (b) Please amend claim 31 to read:

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31. An in vivo method for screening a suspected mimetic of anthrax lethal factor (LF) for mitogen activated protein kinase kinase (MAPKK) protease activity, the method comprising the steps of:

- (i) contacting the suspected LF mimetic with a living cell having an activated mitogen activated protein kinase (MAPK) signal transduction pathway; and
- (ii) assaying for the level of MAPKK protease activity.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative Carol A. Fang on February 13, 2006.

(a) Please cancel claim 32.

(b) Please amend claim 31 to read:

31. A method for screening a suspected mimetic of anthrax lethal factor (LF) for mitogen activated protein kinase kinase (MAPKK) protease activity, the method comprising the steps of:

- (i) contacting the suspected LF mimetic with a cell in vitro or with an ex vivo cell, wherein the cell has an activated mitogen activated protein kinase (MAPK) signal transduction pathway; and
- (ii) assaying for the level of MAPKK protease activity.

(c) Please amend claim 41 to read:

41. The method of claim 39, wherein the MAPKK1 or MAPKK2 is recombinant.